DOCKET NO.: DRPK-0003 **Application No.:** 10/616,247

Office Action Dated: January 3, 2006

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Original) A method providing long term pain management, the method comprising the steps of:

surgically implanting a catheter to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure;

surgically implanting an implantable pump and reservoir in subcutaneous tissue, wherein a proximal end of the catheter, and the reservoir, are in communication with the pump; and

operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site, whereby pain management is provided.

- 2. (Original) The method of claim 1, wherein the neural structure is a brachial plexus nerve complex.
- 3. (Original) The method of claim 2, wherein the catheter is implanted using an axillary approach.
- 4. (Original) The method of claim 2, wherein the catheter is implanted using a subclavian, interscalene or infraclavicular approach.
- 5. (Original) The method of claim 2, wherein implanting the catheter comprises the steps of:

placing a bore needle in communication with a grounding wire of a nerve stimulator; inserting the bore needle within a facial sheath of the brachial plexus; stimulating the bore needle to verify adequate placement within the facial sheath; inserting an arterial line wire through the bore needle;

stimulating the arterial line to verify arterial line location adjacent to the brachial plexus; and

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advancing the catheter over the arterial line and removing the arterial line.

6. (Original) The method of claim 5, wherein implanting the pump and reservoir further comprises the steps of:

making a first incision in skin and subcutaneous tissue at an arterial line skin penetration location;

making a second incision, creating a subcutaneous pocket, and inserting the pump into the pocket;

creating a subcutaneous tunnel between the pocket and the first incision; and threading the catheter through the subcutaneous tunnel to the pocket and attaching the catheter to the pump.

- 7. (Original) The method of claim 5, wherein the bore needle has a conductive protrusion located at a base thereof and extending therefrom to create an angle therebetween to facilitate attachment to the grounding wire of the nerve stimulator.
- 8. (Original) The method of claim 1, wherein the neural structure is a gasserian ganglion, a nasociliary nerve, a long ciliary nerve, an anterior ethmoidal nerve, a subraorbital nerve, a supratrochlear nerve, a maxillary nerve, an infraorbital nerve, a sphenopalantine nerve, a mandibular nerve, an inferior alveolar nerve, a lingual nerve, an auriculotemporal nerve, a masseter nerve or a mental nerve.
- 9. (Original) The method of claim 1, wherein the neural structure is a cervical plexus, a greater occipital nerve, a lesser occipital nerve, a greater auricular nerve, a stellate ganglion or a glassopharyngeal nerve.
- 10. (Original) The method of claim 1, wherein the neural structure is a brachial plexus with the catheter implanted using an interscalene approach, a brachial plexus with the catheter implanted using a supraclavicular approach, a brachial plexus with the catheter implanted using an infraclavicular approach, a brachial plexus with the catheter implanted using an axillary approach, a radial nerve, a median nerve, an ulnar nerve or a digital nerve.

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11. (Original) The method of claim 1, wherein the neural structure is a splanchnic nerve, a thoracic sympathetic ganglion or an intercostal nerve.

- 12. (Original) The method of claim 1, wherein the neural structure is a lumbar sympathetic ganglion, a celiac plexus, an ilioinguinal nerve, an iliohypogastric nerve or a genitofemoral nerve.
- 13. (Original) The method of claim 1, wherein the neural structure is a sciatic nerve, a femoral nerve, a lateral femoral cutaneous nerve, an obturator nerve, a common peroneal nerve, a saphanous nerve, a tibial nerve, a deep peroneal nerve, a superficial peroneal nerve, a superficial saphaneous nerve or a superficial sural nerve.
- 14. (Original) The method of claim 1, wherein the catheter is lined with a metal strip conducive to electrical conduction.
- 15. (Original) The method of claim 14, wherein the metal strip is stimulated to verify adequate catheter placement adjacent to the neural structure.
- 16. (Original) The method of claim 1, wherein the medication is selected from the group consisting of bupivacaine, tetracaine and lidocaine.
- 17. (Original) The method of claim 1, wherein the medication is selected from the group consisting of opiods, antispasmodics, alpha 2 agonists and local anesthetics.
- 18. (Original) The method of claim 1, wherein the neural structure is in a thoracic region.
- 19. (Original) The method of claim 1, wherein the neural structure is an intercostal, interpleural, or paravertebral nerve complex.

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20. (Original) The method of claim 19, wherein implanting the catheter comprises the steps of:

inserting a bore needle into skin and contacting a transverse process; walking the bore needle cephalad off a superior boarder of the transverse process; inserting the bore needle through a superior costotransverse ligament and into the paravertebral space; and

advancing the catheter through the bore needle and into the paravertebral space.

- 21. (Original) The method of claim 1, wherein the neural structure is peripheral to a central nervous system.
- 22. (Original) A closed system providing long term pain management, comprising:

a surgically implanted catheter having a discharge portion lying in a neural structure peripheral to a central nervous system; and

an implantable pump and reservoir located in subcutaneous tissue, wherein a proximal end of the catheter, and the reservoir, are in communication with the pump and the pump is operated to deliver a predetermined dosage of medication through the discharge portion of the catheter into the peripheral neural structure, thereby alleviating pain and providing pain management.

- 23. (Original) The system of claim 22, wherein the medication is one of an opioid, antispasmodic, alpha 2 agonist or local anesthetic.
- 24. (Original) The system of claim 22, wherein the medication is selected from the group consisting of an opioid, antispasmodic, alpha 2 agonist and a local anesthetic.
- 25. (Original) The system of claim 22, wherein the medication is a combination of tetracaine, clonidine and baclofen.

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26. (Original) The system of claim 25, wherein the predetermined dosage of medication is approximately between 10-25 mg/day of tetracaine, approximately between 50-100 mcg/day of clonidine, and approximately between 50-100 mcg/day of baclofen.

- 27. (Original) The system of claim 22, where the catheter has an embedded and electrically conductive material throughout the catheter length sufficient to enable electrical conduction, the material facilitating stimulation to verify a catheter distal end location adjacent to the neural structure.
- 28. (Original) A surgical needle for use in inserting a catheter, comprising: an electrically conductive shaft having a first end adapted to enter a facial sheath of a neural structure, a second end, wherein the shaft has an interior channel running longitudinally therethrough; and

an electrically conductive protrusion extending from the shaft to create a corner therebetween, the protrusion facilitating connection of the needle to a nerve stimulator.

- 29. (Original) The surgical needle of claim 28, wherein the protrusion is adapted to be operatively connected to a clip located at a distal end of a grounding wire of a nerve stimulator.
- 30. (new) The method of claim 1, wherein the catheter is implanted using a needle, the needle comprising:

an electrically conductive shaft having a first end adapted to enter a facial sheath of a neural structure, a second end, wherein the shaft has an interior channel running longitudinally therethrough; and

an electrically conductive protrusion extending from the shaft to create a corner therebetween, the protrusion facilitating connection of the needle to a nerve stimulator.

31. (new) The method of claim 30, wherein the protrusion of the needle is adapted to be operatively connected to a clip located at a distal end of a grounding wire of a nerve stimulator.